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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,427	11/22/2004	Kirsten Bojsen	5559.214-US	9508
25908 7590 03/22/2007 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER NASHED, NASHAAT T	
			ART UNIT	PAPER NUMBER
			1656	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		03/22/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,427	BOJSEN ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-38 are pending and under consideration in this Office action.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 and 27, drawn to a lipolytic enzyme variant of a parent lipase from *Humicola lanuginosa* comprising an amino acid substitution at E1 + G91 + N94 + D96 + E99 + G225 + G263 + L264 + I264 + I265 + 266 + T267 + L269, classified in class 435, subclass 196.
- II. Claims 8, and 14-19, drawn to a lipolytic enzyme variant of a parent lipase comprising an alteration at an amino acid residue within 10 Angstrom units of the C-atom at the sn2 position of the glycerol part of triglyceride substrate, classified in class 435, subclass 196.
- III. Claim 9, drawn to a lipolytic enzyme variant of a parent lipase comprising an alteration at an amino acid residue in the lid region, classified in class 435, subclass 196.
- IV. Claim 10, drawn to a lipolytic enzyme variant of a parent lipase comprising an alteration at active site His residue and having an altered activity on ester bond, classified in class 435, subclass 196.
- V. Claim 11, drawn to a lipolytic enzyme variant of a parent lipase comprising an alteration at a position with 10 amino acid residues of the C-terminal and having altered activity, classified in class 435, subclass 196.
- VI. Claim 12, drawn to a lipolytic enzyme variant of a parent lipase from the *Humicola* family having 80% sequence homology comprising substitution, deletion or insertion at a position corresponding to positions 20, 23, 24, 25, 63, 81, 82, 84, 257, 260, 261, 262 or 266 the lipase from *Humicola lanuginosa*; substitution at positions C268 or L269; and substitution at residues 60, 62, 93, 97, 98, 99, P256, 263, 264, 265, or 267; insertion at position insertion at position 267; and a peptide extension, and having altered activity, classified in class 435, subclass 196.
- VII. Claim 12, drawn to a lipolytic enzyme variant of a parent lipase from the *Zygomycetes* family having 80% sequence homology comprising substitution, deletion or insertion at a position corresponding to positions 20, 23, 24, 25, 63, 81, 82, 84, 257, 260, 261, 262 or 266 the lipase from *Humicola lanuginosa*; substitution at positions C268 or L269; and substitution at residues 60, 62, 93, 97, 98, 99, P256, 263, 264, 265, or 267; insertion at position insertion at position 267; and a peptide extension, and having altered activity, classified in class 435, subclass 196.

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- VIII. Claim 13, drawn to a lipolytic enzyme variant of a parent lysophospholipase from *Aspergillus foetidus* comprising an alteration at a positions 20-25, 56-64, 81-85, 91-98, 255-257, or 259-269, and having altered activity, classified in class 435, subclass 196.
- IX. Claim 13, drawn to a lipolytic enzyme variant of a parent ferulic acid esterase from *Aspergillus niger* comprising an alteration at a positions 20-25, 56-64, 81-85, 91-98, 255-257, or 259-269, and having altered activity, classified in class 435, subclass 196.
- X. Claim 13, drawn to a lipolytic enzyme variant of a parent ferulic acid esterase from *Aspergillus tubigensis* comprising an alteration at a positions 20-25, 56-64, 81-85, 91-98, 255-257, or 259-269, and having altered activity, classified in class 435, subclass 196.
- XI. Claim 13, drawn to a lipolytic enzyme variant of a parent phospholipase A1 from *Aspergillus oryzae* comprising an alteration at a positions 20-25, 56-64, 81-85, 91-98, 255-257, or 259-269, and having altered activity, classified in class 435, subclass 196.
- XII. Claims 20-23, drawn to a DNA encoding a variant lipolytic enzyme, vector, host cell and a method of producing the lipolytic enzyme variant, classified in class 536, subclass 23.2 and classified in class 435, subclass 196.
- XIII. Claim 24, drawn to a process for preparing dough, classified in class 426, subclass 531.
- XIV. Claim 25, drawn to a process for reducing the content of phospholipids in an edible oil, classified in class 435, subclass 271.
- XV. Claim 26, drawn to a process of improving the filterability of an aqueous solution, classified in class 435, subclass 262.
- XVI. Claim 29, drawn to a method of producing lipolytic enzyme variant by mutation within 10 Angstrom of the sn2 position, classified in class 435, subclass 19.
- XVII. Claim 30, drawn to a method of producing lipolytic enzyme variant having the serine protease triad by aligning a selected lipase with the lipase structure of *Rhizomucor miehei*, classified in class 435, subclass 19 and class 702, subclass 27.

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- XVIII. Claims 31 and 35-37, drawn to a method of producing lipolytic enzyme variant by making an alteration at the C-terminus residues of the active site His residue, classified in class 435, subclass 19. Claim 36 is presumed to be correctly dependent on claim 37. If it is not, it will be incorporated to the appropriate invention upon correcting the dependency.
- XIX. Claim 32, drawn to a method of producing lipolytic enzyme variant by mutation within the C-terminal 10 amino acids, classified in class 435, subclass 19.
- XX. Claim 33, drawn to a method of producing lipolytic enzyme variant by mutation within the lid region, classified in class 435, subclass 19.
- XXI. Claims 34 and 38, drawn to a method of producing lipolytic enzyme variant of the *Humicola* family by mutation at amino acid residues corresponding to residues 20-25, 56-64, 81-85, and 255-269 of the lipase from *Humicola lanuginosa*, classified in class 435, subclass 19. Claim 38 was presumed to be dependent on claim 34 and not claim 39 because no claim 39 is pending in the case.
- XXII. Claims 34 and 38, drawn to a method of producing lipolytic enzyme variant of the *Zygomycetes* family by mutation at amino acid residues corresponding to residues 20-25, 56-64, 81-85, and 255-269 of the lipase from *Humicola lanuginosa*, classified in class 435, subclass 19. Claim 38 was presumed to be dependent on claim 34 and not claim 39 because no claim 39 is pending in the case.

Inventions I-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to different molecules having different structures and altered function and would require separate searches in the patent and non-patent literature.

Inventions XII and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to different molecules having different structures and function, and would require separate searches in the patent and non-patent literature.

Inventions II-XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the

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different inventions are directed to different molecules having different structures and function and would require separate searches in the patent and non-patent literature.

Inventions XIII-XV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product is clearly can be used in different methods as each of the independent methods of inventions XIII-XVI uses the product of invention I.

Inventions II-XI and XIII-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different methods of inventions XIII-XVI do not utilize the lipase variants of inventions II-XI.

Inventions III-XII and I, and that of invention XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different methods of inventions III-XII and I are not produced by the method of invention XVI.

Inventions II and XVI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention II can be obtained by different method such as random mutagenesis and screening.

Inventions I-XII and that of invention XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different products of inventions I-XII are not produced by the method of invention XVII.

Inventions I-III and V-XII and that of invention XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different products of inventions I-III and V-XII are not produced by the method of invention XVIII.

Inventions IV and XVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

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process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention IV can be obtained by a different method such as random mutagenesis and screening.

Inventions I-IV and VI-XII and that of invention XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, none of the different products of inventions I-IV and VI-XII is produced by the method of invention XVIII.

Inventions V and XIX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention V can be obtained by different method such as random mutagenesis and screening.

Inventions II, I, and IV-XII and that of invention XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, none of the different products of inventions II, I and IV-XII is produced by the method of invention XX.

Inventions III and XX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention III can be obtained by different method such as random mutagenesis and screening.

Inventions I-V and VII-XII and that of invention XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, none of the different products of inventions I-V and VII-XII is produced by the method of invention XXI.

Inventions VI and XXI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention VI can be obtained by different method such as random mutagenesis and screening.

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Inventions VII and XXII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention VII can be obtained by different method such as random mutagenesis and screening.

Inventions XIII-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different products of inventions are independent methods having different steps and product.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: Each of inventions I-XXII is directed to either multiple variant lipase mutants or method of making and using said lipase, wherein the mutation are selected at different part of a generic lipase or from a genus of lipases, and wherein the mutation takes place at different sites in the molecule producing different effects. The species are independent or distinct because the mutations are expected to have different effect on the catalytic activity of the said lipase and alter its substrate specificity. Thus, each product lipase will have different function.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic. Applicants are required to identify one of the following:

- (a) For inventions XIII-XV, and I applicants are required to identify specific mutant at positions E1 + G91 + N94 + D96 + E99 + G225 + G263 + L264 + I264 + I265 + 266 + T267 + L269.
- (b) For inventions II and XVI, applicants elect one alteration at an amino acid residue within 10 Angstrom units of the C-atom at the sn2 position.

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- (c) For inventions III and XX, applicants elect an alteration at an amino acid residue in the lid region.
- (d) For inventions IV and XVIII, applicants elect a specific alteration at one of the active site His residues.
- (e) For inventions V and XIX, applicants elect a specific alteration at one of the 10 amino acid residues at the C-terminal.
- (f) For inventions VI, VII, XXI, and XXII, applicants elect one specific alteration.
- (g) For invention XVII, no election of species required.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

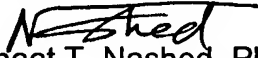
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656